## NOTICE IS HEREBY GIVEN

The State Board of Equalization, pursuant to the authority vested in it by section 15606(a) of the Government Code, proposes to amend Regulation 1591, Medicines and Medical Devices, in Title 18, Division 2, Chapter 4, of the California Code of Regulations, relating to sales and use tax. A public hearing on the proposed regulation will be held in Room 121, 450 N Street, Sacramento, at 1:30 p.m., or as soon thereafter as the matter may be heard, on December 18, 2002. At the hearing, any person interested may present statements or arguments orally or in writing relevant to the proposed regulatory action. The Board will consider written statements or arguments if received by December 18, 2002.

## INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Current law, Revenue and Taxation Code section 6369, provides an exemption from tax for sales of medicines, as defined, under defined conditions. The statute provides that prosthetic and orthotic devices qualify as medicines within the meaning of the statute if they are worn on the body of the patient and perform other specified functions. The statute also provides that article implanted in the body of the patient must be permanently implanted, among other criteria, in order to qualify as medicines within the meaning of the statute.

Regulation 1591, Medicines and Medical Devices, is proposed to be amended to interpret, implement and make specific Revenue and Taxation Code section 6369. Amendments are proposed to (1) provide that prosthetic and orthotic devices qualify as medicines if they come into sustained physical contact with the body of the patient (and satisfy the other criteria in the statute; (2) sales of Continuous Passive Motion Devices are exempt from tax; (3) move the exemption for sales of certain enteral feeding devices from subdivision (b) to subdivision (e) for clarity; and (4) provide that sales of tissue expanders are exempt from tax under defined conditions, and to correct clerical errors; and (5) specify that shoe inserts are excluded from the term "orthotic devices."

## COST TO LOCAL AGENCIES AND SCHOOL DISTRICTS

The State Board of Equalization has determined that the proposed amendment does not impose a mandate on local agencies or school districts. Further, the Board has determined that the proposed action will result in no direct or indirect cost or savings to any State agency, any costs to local agencies or school districts that are required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of Title 2 of the Government Code or other non-discretionary costs or savings imposed on local agencies, or cost or savings in federal funding to the State of California.

## EFFECT ON BUSINESS

Pursuant to Government Code section 11346.5(a)(8), the Board of Equalization makes an initial determination that the adoption of the amendment to Regulation 1591 will have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The adoption of the proposed amendment to this regulation and the proposed regulations will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California.

The proposed regulations may affect small business.

## COST IMPACT ON PRIVATE PERSON OR BUSINESSES

That Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

## SIGNIFICANT EFFECT ON HOUSING COSTS

No significant effect.

## FEDERAL REGULATIONS

Regulation 1591 and the proposed changes have no comparable federal regulations.

#### **AUTHORITY**

Section 7051, Revenue and Taxation Code.

## REFERENCE

Section 6369 Revenue and Taxation Code.

## CONTACT

Questions regarding the substance of the proposed regulation should be directed to Ms. Mariflor Jimenez, telphone (916) 324-2952, fax (916) 322-2958, e-mail <a href="Mariflor.Jimenez@boe.ca.gov">Mariflor.Jimenez@boe.ca.gov</a> or MIC:50, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0050.

Written comments for the Board's consideration, notice of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed administrative action should be directed to Ms. Diane Olson, Regulations Coordinator, telephone (916) 322-9569, fax (916) 324-3984, e-mail <u>Diane.Olson@boe.ca.gov</u> or Ms. Karen Anderson, Contribution Disclosures Analyst, telephone (916) 327-1798, e-mail <u>Karen.Anderson@boe.ca.gov</u> or by mail at State Board of Equalization, Attn: Diane Olson or Karen Anderson, MIC:80, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0080.

# **ALTERNATIVES CONSIDERED**

The Board must determine that no reasonable alternative considered by it or that has been otherwise identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed, or be as effective and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an initial statement of reasons and an underscored version (express terms) of the proposed regulation. Both of these documents and all information on which the proposal is based are available to the public upon request. The Rulemaking file is available for public inspection at 450 N Street, Sacramento, CA. The notice, initial statement of reasons and express terms of the proposed regulation are available on the Internet at the Board's web site <a href="http://www.boe.ca.gov">http://www.boe.ca.gov</a>.

## AVAILABILITY OF FINAL STATEMENT OF REASONS

The final statement of reasons will be made available on the Internet at the Board's web site following public hearing of the proposed regulation. It is also available for your inspection at 450 N Street, Sacramento, CA.

## ADDITIONAL COMMENTS

Following the hearing, the State Board of Equalization may, in accordance with the law, adopt the proposed regulations if the text remains substantially the same as described in the text originally made available to the public. If the State Board of Equalization makes modifications which are substantially related to the originally proposed text, the Board will make the modified text, with the changes clearly indicated, available to the public for fifteen days before adoption of the regulation. The text of any modified regulation will be mailed to those interested parties who commented on the proposed regulatory action orally or in writing or who asked to be informed of such changes. The modified regulation will be available to the public from Ms. Olson. The State Board of Equalization will consider written comments on the modified regulation for fifteen days after the date on which the modified regulation is made available to the public.

Date: September 27, 2002

STATE BOARD OF EQUALIZATION Deborah Pellegrini Chief, Board Proceedings Division